K122539

510(k) Summary

APR 19 2013

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1.0 Submitter Information

Owner	Siemens Healthcare Diagnostics, Inc. Point of Care (POC) Business Unit 2 Edgewater Drive Norwood, MA 02062
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Date Summary Prepared	March 21, 2013

2.0 Device Information

Proprietary Name	RAPIDPoint® 400/405/500 Systems
Common Name	Pleural Fluid pH
Main Classification Name	Blood gases (PCO2, PO2) and blood pH test system 21 CFR 862.1120, Class II Product Code CHL
Subsequent Classifications	

3.0 Predicate Device

	Predicate Device
Device Name	ABL835 FLEX Analyzer With Pleural pH
Common Name	Pleural Fluid pH
510(k) Number	K110416
Manufacturer	Radiometer Medical ApS

4.0 Device Description

The RP400/405/500 system is a point-of-care and laboratory testing blood gas analyzer and currently measures a variety of parameters. With this planned release of software, the ability to measure pH in Pleural Fluid will be added to the system.

The pleural fluid pH measurement provides important information for the diagnosis of exudative pleural effusions. The RAPIDPoint® 400/405/500 system is intended for in vitro testing of pleural fluid samples for the pH parameter. This test system is intended for use in point of care or laboratory settings.

Pleural fluid pH testing follows the same principles as whole blood pH testing. The notation of pH expresses the hydrogen ion activity in a solution as the negative logarithm of the hydrogen ion concentration. The pleural fluid pH measurement uses the potentiometric method using ion selective electrode (ISE) technology.

5.0 Intended Use Statement

RAPIDPoint® 400/405/500 systems are intended for in vitro testing of pleural fluid samples for the pH parameter. Test systems are intended for use in point of care or laboratory settings.

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.

6.0 Summary Comparison of Technological Characteristics

	Feature	**RAPIDPoint® 400/405/500 Pleural Fluid pH (Modified Device)**	**ABL835 FLEX Analyzer With Pleural pH (Predicate Device)**
	Intended Use	RAPIDPoint® 400/405/500 systems are intended for in vitro testing of pleural fluid samples for the pH parameter. Test systems are intended for use in point of care or laboratory settings. The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions. The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.	Same without point of care testing.
	Principle of Operation	Blood gas analyzer	Same
	Test Principle	Potentiometric	Same
	Measured Parameter	pH in Pleural Fluid	Same

6.0 Summary Comparison of Technological Characteristics

Feature	RAPIDPoint® 400/405/500 Pleural Fluid pH (Modified Device)	ABL835 FLEX Analyzer With Pleural pH (Predicate Device)
Parameter Nomenclature	pH in Pleural Fluid	Same
Technology	Pleural fluid pH measurement uses the potentiometric method using ion selective electrode (ISE) technology	Same
Specimen Type	Pleural Fluid	Same
Expected Values*†‡	The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.	Same
Reported Output	pH units	Same
Reporting Range	7.000 to 7.500	Same
Calibration	2 point calibration using automated on-board reagent	2 point liquid calibration
Main Test Steps	Select 'Pleural Fluid' button. Collect sample, insert device into sample luer, & select "Start"	Same ('Other Fluids' button)

* Lesho EP, Roth BJ. *Chest* (1997) 5, 1291 – 1292.
† Chandler TM, McCoskey EH, Byrd RP, Roy TM. *Southern Medical Journal* (1999) 92, 214 – 217.
‡ Hooper C, Lee YC, Maskell N. BTS Pleural Guideline Group. *Thorax* (2010) 65:Suppl 2: ii4-17.

7.0 Test Principle

Pleural fluid pH testing follows the same principles as whole blood pH testing. The notation of pH expresses the hydrogen ion activity in a solution as the negative logarithm of the hydrogen ion concentration. The pleural fluid pH measurement uses the potentiometric method using ion selective electrode (ISE) technology.

8.0 Performance Characteristics

Analytical Performance

a. Precision / Reproducibility

The Precision study consisted of two runs per day, an n=2 per sample run on the RP400/405/500 and performed over the course of 20 days for an n of 80. Pleural fluid samples were buffered and the tension of CO_2 altered to three levels of pH within 7.0 to 7.5 units. All were then stored frozen until the time of use.

Each run performed in Pleural Fluid mode and spaced a minimum of two hours apart, contained Calibration Verification Material (CVM) and pleural fluid samples. Complete QC

Level 2 was analyzed within the center of each run to verify instrument performance. Results for CVM controls and pleural fluid pH are contained in the tables below:

Precision with Controls

Level	n	Mean	WRSD*	% WRCV	Total SD†	% Total CV
RP400						
2	80	7.091	0.003	0.0	0.004	0.1
3	80	7.312	0.002	0.0	0.002	0.0
RP405						
2	80	7.102	0.004	0.1	0.004	0.1
3	80	7.327	0.002	0.0	0.003	0.0
RP500						
2	80	7.098	0.002	0.0	0.004	0.1
3	80	7.324	0.002	0.0	0.004	0.0

Precision with Pleural Fluid

Level	n	Mean	WRSD*	% WRCV	Total SD†	% Total CV
RP400						
Low	80	7.102	0.010	0.1	0.011	0.2
Mid	80	7.284	0.010	0.1	0.011	0.2
High	80	7.469	0.007	0.1	0.008	0.1
RP405						
Low	80	7.102	0.009	0.1	0.011	0.2
Mid	80	7.289	0.012	0.2	0.012	0.2
High	80	7.473	0.007	0.1	0.007	0.1
RP500						
Low	80	7.08	0.006	0.1	0.016	0.2
Mid	80	7.26	0.011	0.2	0.018	0.2
High	80	7.45	0.011	0.1	0.019	0.3

* WRSD = within-run standard deviation
% WRCV = percent within-run coefficient of variation
† Total SD = total standard deviation
% Total CV = percent total coefficient of variation

The sponsor performed a Precision study using typical point of care (POC) operators at three sites running pleural fluid samples on the RP400/405/500 systems. The testing was performed in Pleural Fluid mode over a minimum of 1 day, 3 runs per day, with each run separated by two hours to simulate several days and 5 replicates per run for each of the three levels across the reportable pleural fluid pH range (Low, Mid, High) for a total N = 45. All pleural fluid samples were stored frozen at -70°C or below individually until the time of use. Results are contained in the table below:

Precision with Pleural Fluid (Point of Care Study – Three Sites)

Level	n	Mean	WRSD*	% WRCV	Total SD†	% Total CV
RP400						
Low	45	7.121	0.014	0.19	0.03	0.37
Mid	45	7.295	0.012	0.16	0.02	0.21
High	45	7.464	0.019	0.26	0.02	0.28
RP405						
Low	45	7.110	0.019	0.26	0.03	0.42
Mid	45	7.289	0.011	0.15	0.02	0.21
High	45	7.463	0.017	0.23	0.02	0.28
RP500						
Low	45	7.109	0.013	0.19	0.02	0.35
Mid	45	7.285	0.013	0.18	0.02	0.24
High	45	7.463	0.014	0.18	0.02	0.22

* WRSD = within-run standard deviation
% WRCV = percent within-run coefficient of variation
† Total SD = total standard deviation
%Total CV = percent total coefficient of variation

b. Detection Limit

Detection limit for pleural fluid pH was established in the method comparison study, Section e. below, and for whole blood pH in the previously cleared submission (K002738). The measuring range for pleural fluid pH samples is 7.0 to 7.5.

c. Analytical Specificity

Analytical specificity was established in the previously cleared submission (K002738).

d. Linearity/assay reportable range

Linearity data for pleural fluid collected in the comparison study (see Section e. Method Comparison Studies below) was used to demonstrate linearity on the RP400/405/500 analyzer. Linear regression analysis of the results yielded the following:

RP400: $y = 1.066x (-0.437)$, $r^2 = 0.99$

RP405: $y = 1.008x (-0.009)$, $r^2 = 0.95$

RP500: $y = 1.059x (-0.373)$, $r^2 = 0.99$

Comparison Studies

e. Method Comparison with Predicate Device

The sponsor performed method comparison studies at 3 point of care (POC) clinical sites using at least 3 typical POC operators and one RP405 instrument per site vs. the ABL835 FLEX predicate device. Multiple cartridges and reagent lots were used for this study. All sites were data collection (testing) sites. All specimens were de-identified, leftover samples, collected both prospectively and retrospectively. Less than 20% of the samples

in the study were altered samples. Linear regression analysis was used to determine the coefficient of determination (r^2) and to determine the slope and intercept. The results for the RP405 vs. the predicate device met the acceptance criteria and are contained in the table below:

Statistical Summary of RP405 vs. an ABL 835 FLEX System

n	Slope	Intercept	RMSE	r^2	Sample Range
142	1.008	-0.009	0.030	0.95	7.000 – 7.466

RMSE = Root Mean Square Error r^2 = Coefficient of Determination

The sponsor performed an additional Method Comparison study using typical POC operators at three sites with a minimum of 40 pleural fluid samples per site run in duplicate across the pleural fluid pH reporting range of 7.0 to 7.5 on the RP400 and RP500 vs. the ABL835 FLEX predicate device. Linear regression analysis was used to determine the coefficient of determination (r^2) and to determine the slope and intercept. The results for the RP400 and RP500 vs. the predicate device met the acceptance criteria and are contained in the table below:

Statistical Summary of RP400, RP500 vs. an ABL 835 FLEX System

n	Slope	Intercept	RMSE	r^2	Sample Range
RP400					
122	1.066	-0.437	0.014	0.99	7.011 – 7.458
RP500					
122	1.059	-0.373	0.016	0.99	7.011 – 7.452

RMSE = Root Mean Square Error r^2 = Coefficient of Determination

f. Matrix Comparison

Not applicable.

Clinical Studies

g. Clinical Sensitivity

Not applicable

h. Clinical Specificity

Not applicable

Clinical Cut-off

Not applicable

Expected Values *†‡/ Reference Range

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.

* Lesho EP, Roth BJ. *Chest* (1997) 5, 1291 – 1292.
† Chandler TM, McCoskey EH, Byrd RP, Roy TM. *Southern Medical Journal* (1999) 92, 214 – 217.
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9.0 Instrument Name:

RAPIDPoint 400/405/500 Blood Gas Analyzer

10.0 System Descriptions

Modes of Operation

Pleural Fluid (PF) pH is a new sample type offered on the RAPIDPoint® 400/405/500 (RP400/405/500) blood gas system. The RP400/405/500 system is a point-of-care and laboratory testing blood gas analyzer. Single testing.

Specimen Identification

Samples are identified by barcode.

Specimen Sampling and Handling

Users follow the same sample handling process already in place for measuring other parameters on the blood gas analyzer. Users can analyze samples using the sample collection devices and pleural fluid is collected in a syringe.

Calibration

There is no unique calibration measurement for pleural fluid pH. The pH calibration measurement is used for pleural fluid pH. The targeted calibration points for pH are:

- Calibration Point: 6.8
- Slope Point: 7.4

Quality Control

No unique RapidQC® Complete or CVM® control materials are required for pleural fluid pH. The AutomaticQC cartridge available with the release of the System Software version 3.8 (2.1 on RP500) supports the use of pleural fluid pH.

No new or modified Quality Control (QC) procedures are required to measure pleural fluid pH. The external quality controls, RAPID QC Complete, used in validation are commercially available and were cleared under the 510(k) number K970956.

Other Supportive Instrument Performance Characteristics Data Not Covered in the "Performance Characteristics" Section above:

None

11.0 Conclusion

The results of these studies demonstrate that the RAPIDPoint 400/405/500 blood gas analyzer is similar to the predicate in both Technological Characteristics and Intended Use and is therefore substantially equivalent. The data presented is a summary of external clinical evaluation, internal laboratory evaluation, and software development information. The RAPIDPoint 400/405/500 performance was shown to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 19, 2013

Siemens Healthcare Diagnostics, Inc.
C/O Amy Goldberg
Point of Care (POC) Business Unit
2 Edgewater Drive
NORWOOD MA 02062

Re: K122539
Trade/Device Name: RAPIDPoint® 400/405/500 Systems
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL
Dated: March 21, 2013
Received: March 22, 2013

Dear Ms. Goldberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122539

Device Name: RAPIDPoint® 400/405/500 Systems

Indications for Use:

RAPIDPoint® 400/405/500 systems are intended for *in vitro* testing of pleural fluid samples for the pH parameter. Test systems are intended for use in point of care or laboratory settings.

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

The following critical value applies to pleural fluid pH: pH > 7.3 is measured in uncomplicated parapneumonic effusions. All pleural fluids with a pH measurement < 7.3 are referred to as complicated parapneumonic effusions, and are exudative in nature.

Prescription Use _X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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